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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

RAWLINGS, STEPHEN L

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 08/07/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/676,718

Applicant(s)

GLADYSHEV ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2000 and 23 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26, 29-34 and 36-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-26, 29-34 and 36-65 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Election facsimile cover sheet*.

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DETAILED ACTION

1. The amendment filed September 28, 2000 (Paper No. 5) is acknowledged and has been entered. Claims 27, 28, and 35 have been canceled. Claims 1-6, 12, 13, 17-19, 21, 24-26, 29, 30, 33, 34, 36-40 have been amended. Claims 42-65 have been added.

2. The amendment filed July 18, 2002 in Paper No. 7 is acknowledged and has been entered.

3. Claims 1-26, 29-34, and 36-65 are pending in the application and are currently subject to restriction and an election requirement.

Election/Restrictions

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-3, 17, 18, 41, 63, and 64, insofar as the claims are drawn to a polypeptide or a fragment thereof and a composition comprising said polypeptide or fragment thereof, wherein said polypeptide, wherein said polypeptide comprises an amino acid sequence that is at least 70% identical to SEQ ID NO: 1, classified in class 530, subclass 350 and class 514, subclass 2.

Group II. Claims 1-3, 17, 18, 41, 63, and 64, insofar as the claims are drawn to a polypeptide or a fragment thereof and a composition comprising said polypeptide or fragment thereof, wherein said polypeptide, wherein said polypeptide comprises an amino acid sequence that is at least 70% identical to SEQ ID NO: 4, classified in class 530, subclass 350 and class 514, subclass 2.

Group III. Claims 1-3, 17, 18, 41, 63, and 64, insofar as the claims are drawn to a polypeptide or a fragment thereof and a composition

comprising said polypeptide or fragment thereof, wherein said polypeptide, wherein said polypeptide comprises an amino acid sequence that is at least 70% identical to SEQ ID NO: 9, classified in class 530, subclass 350 and class 514, subclass 2.

Group IV. Claims 6-8 and 11, insofar as the claims are drawn to a binding agent and a kit comprising said binding agent, wherein said binding agent specifically binds to a polypeptide comprising at least 5 consecutive amino acids of SEQ ID NO: 1, classified, for example, in class 530, subclass 387.9.

Group V. Claims 6-8 and 11, insofar as the claims are drawn to a binding agent and a kit comprising said binding agent, wherein said binding agent specifically binds to a polypeptide comprising at least 5 consecutive amino acids of SEQ ID NO: 4, classified, for example, in class 530, subclass 387.9.

Group VI. Claims 6-8 and 11, insofar as the claims are drawn to a binding agent and a kit comprising said binding agent, wherein said binding agent specifically binds to a polypeptide comprising at least 5 consecutive amino acids of SEQ ID NO: 9, classified, for example, in class 530, subclass 387.9.

Group VII. Claims 9 and 10, insofar as the claims are drawn to a method for detecting or quantifying a polypeptide, wherein said method comprises contacting a sample with a binding agent that specifically binds to a polypeptide comprising at least 5 consecutive amino acids of SEQ ID NO: 1, classified in class 435, subclass 7.1+.

Group VIII. Claims 9 and 10, insofar as the claims are drawn to a method for detecting or quantifying a polypeptide, wherein said method comprises contacting a sample with a binding agent that specifically binds to a polypeptide comprising at least 5 consecutive

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amino acids of SEQ ID NO: 4, classified in class 435, subclass 7.1+.

Group IX. Claims 9 and 10, insofar as the claims are drawn to a method for detecting or quantifying a polypeptide, wherein said method comprises contacting a sample with a binding agent that specifically binds to a polypeptide comprising at least 5 consecutive amino acids of SEQ ID NO: 9, classified in class 435, subclass 7.1+.

Group X. Claims 12-16, 20, 34, 42, and 43, insofar as the claims are drawn to a nucleic acid molecule or fragment thereof comprising an a polynucleotide sequence that is at least 70% identical to SEQ ID NO: 2, classified in class 536, subclass 23.5 and class 536, subclass 24.31.

Group XI. Claims 12-16, 20, 34, 42, and 43, insofar as the claims are drawn to a nucleic acid molecule or fragment thereof comprising an a polynucleotide sequence that is at least 70% identical to SEQ ID NO: 3, classified in class 536, subclass 23.5 and class 536, subclass 24.31.

Group XII. Claims 12-16, 20, 34, 42, and 43, insofar as the claims are drawn to a nucleic acid molecule or fragment thereof comprising an a polynucleotide sequence that is at least 70% identical to SEQ ID NO: 8, classified in class 536, subclass 23.5 and class 536, subclass 24.31.

Group XIII. Claim 19, insofar as the claim is drawn to a method for detecting a nucleic acid molecule, wherein said method comprises contacting a sample with an oligonucleotide comprising at least 15 consecutive nucleotides of SEQ ID NO: 2, classified in class 435, subclass 6.

Group XIV. Claim 19, insofar as the claim is drawn to a method for detecting a nucleic acid molecule, wherein said method comprises

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contacting a sample with an oligonucleotide comprising at least 15 consecutive nucleotides of SEQ ID NO: 8, classified in class 435, subclass 6.

Group XV. Claims 21, 22, 36, 44, 45, 49, 57, and 65, insofar as the claims are drawn to a method for detecting a polymorphism in a nucleic acid molecule, wherein said nucleic acid molecule comprises a polynucleotide sequence that is at least 70% identical to SEQ ID NO: 2 and wherein said method comprises determining a sequence of said nucleic acid molecule, classified in class 435, subclass 6.

Group XVI. Claims 21, 22, 36, 44, 45, 49, 57, and 65, insofar as the claims are drawn to a method for detecting a polymorphism in a nucleic acid molecule, wherein said nucleic acid molecule comprises a polynucleotide sequence that is at least 70% identical to SEQ ID NO: 3 and wherein said method comprises determining a sequence of said nucleic acid molecule, classified in class 435, subclass 6.

Group XVII. Claims 21, 22, 36, 44, 45, 49, 57, and 65, insofar as the claims are drawn to a method for detecting a polymorphism in a nucleic acid molecule, wherein said nucleic acid molecule comprises a polynucleotide sequence that is at least 70% identical to SEQ ID NO: 8 and wherein said method comprises determining a sequence of said nucleic acid molecule, classified in class 435, subclass 6.

Group XVIII. Claims 23 and 50, insofar as the claims are drawn to a method for detecting a polymorphism in a nucleic acid molecule, wherein said nucleic acid molecule encodes the polypeptide of SEQ ID NO: 1 and wherein said method comprises hybridizing a probe that distinguishes polymorphic nucleic acid molecules from

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non-polymorphic nucleic acid molecules, classified in class 435, subclass 6.

Group XIX. Claims 23 and 50, insofar as the claims are drawn to a method for detecting a polymorphism in a nucleic acid molecule, wherein said nucleic acid molecule encodes the polypeptide of SEQ ID NO: 4 and wherein said method comprises hybridizing a probe that distinguishes polymorphic nucleic acid molecules from non-polymorphic nucleic acid molecules, classified in class 435, subclass 6.

Group XX. Claims 23 and 50, insofar as the claims are drawn to a method for detecting a polymorphism in a nucleic acid molecule, wherein said nucleic acid molecule encodes the polypeptide of SEQ ID NO: 9 and wherein said method comprises hybridizing a probe that distinguishes polymorphic nucleic acid molecules from non-polymorphic nucleic acid molecules, classified in class 435, subclass 6.

Group XXI. Claim 24, insofar as the claim is drawn to a method for detecting a polypeptide having an amino acid sequence that is at least 70% identical to SEQ ID NO: 1, classified in class 435, subclass 4.

Group XXII. Claim 24, insofar as the claim is drawn to a method for detecting a polypeptide having an amino acid sequence that is at least 70% identical to SEQ ID NO: 4, classified in class 435, subclass 4.

Group XXIII. Claim 24, insofar as the claim is drawn to a method for detecting a polypeptide having an amino acid sequence that is at least 70% identical to SEQ ID NO: 9, classified in class 435, subclass 4.

Group XXIV. Claims 25, 26, and 55, insofar as the claims are drawn to a method for dietary regulation, wherein said method comprises

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detecting a polypeptide having an amino acid sequence that is at least 70% identical to SEQ ID NO: 1, classified in class 435, subclass 6 or subclass 7.1.

Group XXV. Claims 25, 26, and 55, insofar as the claims are drawn to a method for dietary regulation, wherein said method comprises detecting a polypeptide having an amino acid sequence that is at least 70% identical to SEQ ID NO: 4, classified in class 435, subclass 6 or subclass 7.1.

Group XXVI. Claims 25, 26, and 55, insofar as the claims are drawn to a method for dietary regulation, wherein said method comprises detecting a polypeptide having an amino acid sequence that is at least 70% identical to SEQ ID NO: 9, classified in class 435, subclass 6 or subclass 7.1.

Group XXVII. Claims 29 and 60, insofar as the claims are drawn to a method for dietary regulation, wherein said method comprises determining if a mammal is at increased risk for cancer associated with defects in a polypeptide having an amino acid sequence that is at least 70% identical to SEQ ID NO: 1, classified in class 435, subclass 4.

Group XXVIII. Claims 29 and 60, insofar as the claims are drawn to a method for dietary regulation, wherein said method comprises determining if a mammal is at increased risk for cancer associated with defects in a polypeptide having an amino acid sequence that is at least 70% identical to SEQ ID NO: 4, classified in class 435, subclass 4.

Group XXIX. Claims 29 and 60, insofar as the claims are drawn to a method for dietary regulation, wherein said method comprises determining if a mammal is at increased risk for cancer associated with defects in a polypeptide having an amino acid sequence that is

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at least 70% identical to SEQ ID NO: 9, classified in class 435, subclass 4.

Group XXX. Claims 30-33, 46-48, 56, and 61, insofar as the claims are drawn to a method for determining a subject's risk or susceptibility for developing cancer, wherein said method comprises determining the genotype of a mammalian gene that has at least 70% identity to SEQ ID NO: 2, classified in class 435, subclass 91.2.

Group XXXI. Claims 30-33, 46-48, 56, and 61, insofar as the claims are drawn to a method for determining a subject's risk or susceptibility for developing cancer, wherein said method comprises determining the genotype of a mammalian gene that has at least 70% identity to SEQ ID NO: 3, classified in class 435, subclass 91.2.

Group XXXII. Claims 30-33, 46-48, 56, and 61, insofar as the claims are drawn to a method for determining a subject's risk or susceptibility for developing cancer, wherein said method comprises determining the genotype of a mammalian gene that has at least 70% identity to SEQ ID NO: 8, classified in class 435, subclass 91.2.

Group XXXIII. Claims 37 and 58, insofar as the claims are drawn to a transgenic mouse that over-expresses a nucleic acid molecule encoding at least 5 consecutive amino acids of a polypeptide that is at least 70% identical to SEQ ID NO: 1, classified in class 800, subclass 18.

Group XXXIV. Claims 37 and 58, insofar as the claims are drawn to a transgenic mouse that over-expresses a nucleic acid molecule encoding at least 5 consecutive amino acids of a polypeptide that is at least 70% identical to SEQ ID NO: 4, classified in class 800, subclass 18.

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Group XXXV. Claims 37 and 58, insofar as the claims are drawn to a transgenic mouse that over-expresses a nucleic acid molecule encoding at least 5 consecutive amino acids of a polypeptide that is at least 70% identical to SEQ ID NO: 9, classified in class 800, subclass 18.

Group XXXVI. Claims 38 and 59, insofar as the claims are drawn to a transgenic mouse in which a nucleic acid molecule encoding at least 5 consecutive amino acids of a polypeptide that is at least 70% identical to SEQ ID NO: 1 is functionally deleted, classified in class 800, subclass 18.

Group XXXVII. Claims 38 and 59, insofar as the claims are drawn to a transgenic mouse in which a nucleic acid molecule encoding at least 5 consecutive amino acids of a polypeptide that is at least 70% identical to SEQ ID NO: 4 is functionally deleted, classified in class 800, subclass 18.

Group XXXVIII. Claims 38 and 59, insofar as the claims are drawn to a transgenic mouse in which a nucleic acid molecule encoding at least 5 consecutive amino acids of a polypeptide that is at least 70% identical to SEQ ID NO: 9 is functionally deleted, classified in class 800, subclass 18.

Group XXXIX. Claims 39 and 62, insofar as the claims are drawn to a method for reducing a subject's susceptibility to cancer, wherein said method comprises administering to said subject a polypeptide having an amino acid sequence that is at least 70% identical to SEQ ID NO: 1, classified in class 514, subclass 2.

Group XL. Claims 39 and 62, insofar as the claims are drawn to a method for reducing a subject's susceptibility to cancer, wherein said method comprises administering to said subject a polypeptide having an amino acid sequence that is at least 70% identical to SEQ ID NO: 4, classified in class 514, subclass 2.

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Group XLI. Claims 39 and 62, insofar as the claims are drawn to a method for reducing a subject's susceptibility to cancer, wherein said method comprises administering to said subject a polypeptide having an amino acid sequence that is at least 70% identical to SEQ ID NO: 9, classified in class 514, subclass 2.

Group XLII. Claims 39, 40, and 62, insofar as the claims are drawn to a method for reducing a subject's susceptibility to cancer, wherein said method comprises administering to said subject a nucleic acid molecule comprising SEQ ID NO: 2, classified in class 514, subclass 44.

Group XLIII. Claims 39, 40, and 62, insofar as the claims are drawn to a method for reducing a subject's susceptibility to cancer, wherein said method comprises administering to said subject a nucleic acid molecule comprising SEQ ID NO: 3, classified in class 514, subclass 44.

Group XLIV. Claims 39, 40, and 62, insofar as the claims are drawn to a method for reducing a subject's susceptibility to cancer, wherein said method comprises administering to said subject a nucleic acid molecule comprising SEQ ID NO: 8, classified in class 514, subclass 44.

Group XLV. Claims 51-53, insofar as the claims are drawn to a method for determining if a subject has an increased risk for developing cancer, wherein said method comprises determining if the subject has an abnormally low expression of a polypeptide comprising an amino acid sequence that is at least 70% identical to SEQ ID NO: 1, classified in class 435, subclass 4+.

Group XLVI. Claims 51-53, insofar as the claims are drawn to a method for determining if a subject has an increased risk for developing cancer, wherein said method comprises determining if the subject has an abnormally low expression of a polypeptide comprising an

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amino acid sequence that is at least 70% identical to SEQ ID NO: 4, classified in class 435, subclass 4+.

Group XLVII. Claims 51-53, insofar as the claims are drawn to a method for determining if a subject has an increased risk for developing cancer, wherein said method comprises determining if the subject has an abnormally low expression of a polypeptide comprising an amino acid sequence that is at least 70% identical to SEQ ID NO: 9, classified in class 435, subclass 4+.

Group XLVIII. Claim 54, insofar as the claim is drawn to a method for dietary regulation, wherein said method comprises determining if the subject has an abnormally low expression of a polypeptide comprising an amino acid sequence that is at least 70% identical to SEQ ID NO: 1, classified in class 435, subclass 4+.

Group XLIX. Claim 54, insofar as the claim is drawn to a method for dietary regulation, wherein said method comprises determining if the subject has an abnormally low expression of a polypeptide comprising an amino acid sequence that is at least 70% identical to SEQ ID NO: 4, classified in class 435, subclass 4+.

Group L. Claim 54, insofar as the claim is drawn to a method for dietary regulation, wherein said method comprises determining if the subject has an abnormally low expression of a polypeptide comprising an amino acid sequence that is at least 70% identical to SEQ ID NO: 9, classified in class 435, subclass 4+.

5. The inventions are distinct, each from the other because of the following reasons:

Inventions in groups I-VI, X-XII, and XXXIII-XXXVIII are disclosed as biologically and chemically distinct, unrelated in structure and/or function, and/or made by and/or used in different methods and therefore, the claimed products are distinct.

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Inventions in groups VII-XXXII and XXXIX-L are disclosed as materially different methods that differ at least in objectives, method steps, reagents and/or doses and/or schedules used, response variables, assays for end products and/or results, and criteria for success and therefore, the claimed methods are distinct.

Inventions in groups I-III and groups XXXIX-XLI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed, namely the polypeptide can be used in a materially different process of using that product, such as the process of producing an antibody that specifically binds to said polypeptide.

Inventions in groups IV-VI and groups VII-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed, namely the binding agent can be used in a materially different process of using that product, such as the process of purifying the protein to which the binding agent binds by affinity chromatography.

Inventions in groups X-XII and groups XIII-XVII, XXX-XXXII, and XLII-XLIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed, namely the nucleic acid molecule can be used in a materially different

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process of using that product, such as the process of producing the polypeptide encoded by said nucleic acid molecule.

The inventions in groups I-III and groups VII-XXXII and XLII-L are not at all related because the products of groups I-III are not specifically used in any of the steps of the claimed methods in groups VII-XXXII and XLII-L.

The inventions in groups IV-VI and groups X-XXXII and XXXIX-L are not at all related because the products of groups IV-VI are not specifically used in any of the steps of the claimed methods in groups X-XXXII and XXXIX-L.

The inventions in groups X-XII and groups VII-IX, XVIII-XXIX, XXXIII-XLI, and XLV-L are not at all related because the products of groups XXXIII-XXXVIII are not specifically used in any of the steps of the claimed methods in groups VII-IX, XVIII-XXIX, XXXIII-XLI, and XLV-L.

The inventions in group XI and groups XIII and XIV are not at all related because the products of group XI are not specifically used in any of the steps of the claimed methods in groups XIII and XIV.

The inventions in groups XXXIII-XXXVIII and groups VII-XXXII and XXXIX-L are not at all related because the products of groups XXXIII-XXXVIII are not specifically used in any of the steps of the claimed methods in groups VII-XXXII and XXXIX-L.

6. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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8. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.

Examiner

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DONNA WORTMAN
PRIMARY EXAMINER

slr

August 7, 2002



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